REMARKS

Claims 1-4, 6-10, 14-15 and 28-33 are pending, wherein claims 1, 6-9, 28 and 30 have been amended. No claims were added or cancelled by this amendment. Reconsideration and allowance for the above-identified application are now respectfully requested. Claims 11-13 are currently withdrawn from consideration. Nevertheless, Applicant requests rejoinder of claims 1-13 upon the allowance of claim 1 from which they depend.

Claims 6-9 and 30 were amended to address the claim rejections under 35 U.S.C. § 112. Claims 1 and 28 were amended to specifically recite that which was inherent in the claims as previously presented, *i.e.*, that the "covering ... defines an enclosed space" and the bone growth material is "disposed within the enclosed space" and thereby encapsulated within the enclosed space defined by the covering.

Applicant understands that the choice of whether to use the indefinite articles "A" or "An" rather than the definite article "The" when beginning a dependent claim is a matter of style and not mandated by any rule of which Applicant is aware. Applicant will provide examples of patents issued by the USPTO that use the indefinite article to begin its dependent claims upon request (*e.g.*, U.S. Patent No. 4,863,472 to Tormala et al., relied on as the primary reference in the current Office Action).

The Office Action rejects claims 1-4, 6-10, 14-15 and 28-33 under 35 U.S.C. § 103(a) as being unpatentable over Tormala et al. (U.S. 4,863,472) taken with Silverberg (U.S. 4,755,184) in view of Levy (U.S. 5,292,253) and Vyakarnam et al. (U.S. 6,306,424). In making this rejection, the Office Action does not show where every element recited in the claims is taught or suggested in the prior art.

Claim 1, for example, claims an implant device comprising a dry covering comprised of a water absorbing gelatinizable material that defines an enclosed space and which becomes sticky and gelatinous upon contact with water and a bone growth promoting material disposed within the enclosed space, wherein the dry covering forms an outer cover of the implant device so as to encapsulate the bone growth promoting material within the enclosed space. Claim 1 is unobvious over the applied art because the applied art, either taking singly or in combination, neither teaches nor suggests the combination of elements recited in claim 1.

For example, Tormala et al. neither teaches nor suggests an implant device that includes a dry covering comprised of a water absorbable gelatinized material that defines an enclosed space and which becomes sticky and gelatinous upon contact with water and a bone growth promoting

material disposed within the enclosed space. The Office Action alleges that Tormala et al. discloses an implant device comprising a supporting structure that surrounds granules comprising a water absorbing gelatinizable material. However, the Office Action does not provide any citation within Tormala et al. showing that the materials which comprise the supporting structure is a "water absorbing gelatinizable material". Instead, the Office Action merely assumes that the disclosed materials have this feature without providing any evidence. For example, the Office Action alleges that "polyglycolide, cellulose derivatives or cross-linked collagen derivatives such as cat gut/Katgut" constitute a "water absorbing gelatinizable material". In fact, such materials are not water gelatinizable nor do they "become sticky or gelatinous upon contact with water" as further required by claim 1. Nor does the Office Action even allege that such materials become "sticky and gelatinous upon contact with water". As a result, the Office Action fails to show where Tormala et al. teaches the required feature of a dry covering that "becomes sticky and gelatinous upon contact with water". None of the other references are alleged to provide this missing feature such that the combination of references does not teach or suggest every element recited in claim 1 as previously presented. For this reason, claim 1 as previously presented is not *prima facie* obvious over the applied art.

It would be reasonable to assume that polyglycolide, cellulose derivatives or cross-linked collagen derivatives inherently have the property of becoming sticky and gelatinous upon contact with water. "Polyglycolide" is a well known hydrophobic polymer that is used to form sutures and reabsorbable implant devices and is both insoluble and therefore not gelatinizable in water, as evidenced by the document attached as Exhibit A hereto. It clearly does not become "sticky and gelatinous upon contact with water". Otherwise, polyglycolide would be unsuitable for use in making sutures or implantable devices, such as "anastomisis rings, pins, rods, plates and screws". Exhibit A.

The same is true for the "cellulose derivative" disclosed in Tormala et al., which is exemplified by "SURGICEL", a bandage material sold by Johnson & Johnson. Exhibit B and C. SURGICEL is used to close wounds like ordinary gauze and also includes a hemostatic agent to stop bleeding. It does not become sticky and gelatinous upon contact with water as this behavior would cause the bandage to disintegrate and be unable to perform its intended wound closing function. As evidence that SURGICEL does not become gelatinous and disintegrate when exposed to water, Applicant refers to the document attached hereto as Exhibit B, which states that "[u]nlike gelatin sponges, SURGICEL NU-KNIT Hemostat won't disintegrate during

surgery." The document attached at Exhibit C states that the "high tensile strength [of SURGICEL] means it won't fall apart when inserted through a trocar."

Finally, cross-linked collagen materials such as catgut are also not water gelatinizable and do not become sticky and gelatinous upon contact with water. As evidence of this, Applicant refers to the document attached as Exhibit D hereto. This document states that Catgut is used to make sutures. It is clear that sutures do not become sticky and gelatinous upon contact with water. Otherwise, they would quickly disintegrate and result in wound opening. This is not to say that collagen materials such as catgut or other connective tissues cannot be hydrolyzed and therefore form a material that is gelatinizable in water so as to form a sticky and gelatinous material upon contact with water. As evidence of this, Applicant refers to the document attached as Exhibit E hereto, which refers to both collagen, which is the major component of connective tissue and is a strong water-insoluble polymer, and hydrolyzed collagen, which can become sticky and gelatinous when exposed to water. Tormala et al., however, does not teach or suggest the use of hydrolyzed forms of collagen or cat gut.

In short, Tormala et al. neither teaches nor suggests an implant device that includes a dry covering made from a water absorbing gelatinizable material that becomes sticky and gelatinous upon contact with water. The only remaining issue is whether any other of the cited references teach or suggest a dry covering comprising of a water absorbing gelatinizable material that becomes sticky and gelatinous upon contact with water.

Silverberg is equally deficient as Tormala et al. in this regard. The Office Action states that Silverberg discloses a device having a casing made from "polyglycolide", which is alleged to comprise a "water absorbing gelatinizable material". However, polyglycolide, as discussed above, is a well-known hydrophobic polymer that is neither water soluble, water gelatinizable, or capable of becoming sticky and gelatinous upon contact with water. In support of this, Applicant again refers to the document at Exhibit A, which expressly teaches that polygycolide is "insoluble in water". The polymer has a melting point of 225-230°C and is described as having "an elevated degree of crystallinity around 45-55%", which explains why it is "insoluble in water". It is also described as "insoluble in almost all common organic solvents". In view of the evidence submitted by Applicant, it is clear that the "polyglycolide" casing of Silverberg is not a "water absorbing gelatinizable material" and is certainly not capable of becoming "sticky and gelatinous upon contact with water".

The Office Action also alleges that the "bovine collagen" of Silverberg is a material that

is dry and will become sticky and gelatinous upon contact with water. In view of the document at Exhibit E, however, collagen comes in various forms and is "the most abundant protein in mammals" such as bovine. Exhibit E. The document at Exhibit E further states that "collagen has great tensile strength, and is the main component of fascia, cartilage, ligaments, tendons, bone and teeth." It is clear that none of these materials is a "water absorbing gelatinizable material" that "becomes sticky and gelatinous upon contact with water." Otherwise, mammalian bodies, including all connective tissue, bones and teeth, would inherently fall apart and become a gelatinous ooze in light of the fact that mammalian bodies contain mostly water. Instead, collagen (including bovine collagen) is clearly not water soluble and does not become sticky and gelatinous upon contact with water. Natural collagen must first be hydrolyzed in order to become sticky and gelatinous upon contact with water. There is nothing in Silverberg to suggest that the "bovine collagen" has been hydrolyzed in a manner so as to become a water absorbing gelatinizable material that also becomes sticky and gelatinous upon contact with water. Accordingly, Silverberg neither teaches nor suggests an implant device that includes a dry covering comprised of a water absorbing gelatinizable material that defines an enclosed space and which becomes sticky and gelatinous upon contact with water.

The remaining references were cited for other reasons and therefore do not teach or suggest a dry covering comprised of a water absorbable gelatinizable material that defines an enclosed space and which becomes sticky and gelatinous upon contact with water as required by claim 1. While Levy allegedly teaches the use of a protein gel that can be combined with calcium-containing materials such as hydroxyapatite, such protein gel is not in the form of "a dry covering comprised of a water absorbing gelatinizable material that defines an enclosed space and which become sticky and gelatinous upon contact with water".

Vyakarnam et al. was merely cited for the teaching of packaging implant materials in an appropriate sterilized moisture resistant package for shipment and therefore fails to fill in the deficiencies of the other references. In view of this, claim 1 as amended is unobvious over the applied art.

The dependent claims define additional limitations that may serve to further distinguish over the art of record. For example, claim 4 states that "the water absorbing gelatinizable material is non-resorbable". However, the polymeric materials in Tormala et al. are expressly described as being "resorbable". It would be contrary to Tormala et al. to provide a material as a covering that is "non-resorbable" as required by claim 4.

Claim 28 is similarly patentable over the art of record for the reasons set forth above with respect to claim 1, particularly because the applied art neither teaches nor suggests an implant device that comprises "a dry covering comprised of a water absorbable gelatinizable material that defines an enclosed space and which becomes sticky and gelatinous upon contact with water". Claim 28 is further patentable over the art of record as it further requires a thickener dispersed among the bone growth promoting material which comprises a material that forms a viscous gel or firm putty upon contact with water. Tormala et al., for example, neither teaches nor suggests an implant device that includes a thickener dispersed among bone growth promoting material that forms a viscous gel or firm putty upon contact with water. Instead, Tormala et al. merely teaches that the same resorbable materials used to make the supporting structure can also be mixed with the ceramic powder. Those may act as a "glue-phase between the particles and a composite material". Col. 4, line 65 – Col. 5, line 1. As the resorbable materials disclosed in Tormala et al. are not water absorbing gelatinizable materials that become sticky and gelatinous upon contact with water, they also do not likely form a viscous gel or firm putty upon contact with water but are instead water insoluble materials as discussed above. Polymeric material such as those disclosed in Tormala et al. are certainly capable of acting as a glue-like matrix by heating the polymer to above its melting point and then cooling it so as to form a solid glue-like matrix. However, there is nothing about the term "glue-phase" that implies the material is capable of forming a viscous gel or firm putty upon contact with water. Nor does the Office Action provide any evidence in support of this assertion. Accordingly, for this additional reason Applicant submits that claim 28 is patentable over the art of record.

In the event the Examiner finds any remaining impediment to a prompt allowance of this application that may be clarified through a telephone interview or which may be overcome by examiner amendment, the Examiner is requested to contact the undersigned attorney.

Dated this 16th day of November 2007.

Respectfully submitted,

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